NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE
BOARD OF HEALTH

NOTICE OF ADOPTION OF AMENDMENTS TO VARIOUS PROVISIONS OF ARTICLE 175 OF THE NEW YORK CITY HEALTH CODE

In compliance with Sections 1043(b) and (d) of the New York City Charter, a Notice of Intention to amend Article 175 of the New York City Health Code was published in the City Record on June 21, 2006 and a public hearing was held on July 26, 2006. No one testified and 1 written comment was received. At its meeting on September 26, 2006, the Board of Health adopted the following resolution.

STATUTORY AUTHORITY

These amendments to the New York City Health Code ("Health Code") are adopted pursuant to Sections 556, 558 and 1043 of the New York City Charter ("Charter") and applicable state and federal law. Section 556 of the Charter grants the New York City Department of Health and Mental Hygiene ("Department") jurisdiction to regulate matters affecting health in New York City (NYC). Specifically, Section 556 (c)(11) of the Charter authorizes the Department to regulate all aspects of ionizing radiation within the 5 boroughs of New York City. Sections 558 (b) and (c) of the Charter empower the Board of Health to amend the Health Code and to include in the Health Code all matters to which the Department's authority extends. Section 1043 of the Charter grants rule-making powers to the Department. The New York State (NYS) Sanitary Code (i.e., 10 NYCRR §16.1(b)(3)) delegates radiation licensure regulation to those localities that have a population of more than 2,000,000, provided that said requirements are consistent with NYS Sanitary Code requirements. Section 274 of the Federal Atomic Energy Act of 1954 (the Act) (codified at 42 USC §2021) authorizes "Agreement States" to regulate byproduct material, source material and special nuclear material in quantities not sufficient to form a critical mass. New York State is an "Agreement State" within the meaning of the Act, and the New York City Department of Health and Mental Hygiene is a component of and a party to the relevant Agreement.

STATEMENT OF BASIS AND PURPOSE

In order to maintain compatibility with applicable New York State Sanitary Code and federal regulations, the NYC Health Code is being amended concerning both Radioactive Materials and Radiation Equipment. The Health Code is also being amended to comply with a NYS Comptroller's Audit Report (2001-N-9) recommendation that all new x-ray facilities be inspected and approved by the Department prior to initiating clinical x-ray exams. Finally, the Health Code is being amended to delineate the specific protocols to be followed in calibration of x-ray therapy units, and to specify the content of the x-ray therapy calibration reports to be reviewed by the Department.

Radioactive Materials

The Department's Office of Radiological Health (ORH) licenses and inspects radioactive materials facilities for compliance with Article 175 of the New York City Health Code to protect the health and safety of patients, operators and the general public. There are about 375 licensed sites in New York City possessing radioactive material for medical, academic and research

purposes. ORH inspects these facilities at frequencies of once every one, two or three years depending on the type of usage.

As noted above, New York State is an "Agreement State", which means that NYS and the United States Nuclear Regulatory Commission (NRC) have entered into an agreement under the Atomic Energy Act, which delegates authority to NYS to regulate radioactive material at non-reactor sites within its jurisdiction. The New York State Agreement is comprised of four regulatory programs - New York State Department of Health, New York State Department of Labor, New York State Department of Environmental Conservation, and the New York City Department of Health and Mental Hygiene. The Department, through its Office of Radiological Health, regulates radioactive material for medical, academic and research purposes within the 5 boroughs of New York City.

Each Agreement State program is required to maintain compatibility with the NRC regulatory program.[1] The NRC ensures an adequate level of compatibility through the Integrated Materials Performance Evaluation Program (IMPEP) and conducts a quadrennial review of Agreement State programs. The latest IMPEP review of the NYS program took place in July of 2002.

In the July 2002 IMPEP review, the NRC evaluated each of the four components of the New York State Agreement. NRC findings were presented in its Final Report, dated November 12, 2002. The NRC IMPEP report concluded that certain regulations needed to be incorporated into Article 175 of the New York City Health Code in order to ensure compatibility with NRC regulations. Those regulations that remained to be incorporated were:

- "Revision of the Skin Dose Limit", 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2002 (amending 10 CFR §§ 20.1003; 20.1201).

- "Respiratory Protection and Controls to Restrict Internal Exposures", 10 CFR Part 20 amendment (64 FR 54543; 55524) that became effective February 2, 2000 (amending 10 CFR §§ 20.1003; 20.1701 - 20.1704; adding 20.1705 and amending Appendix A to Part 20).

Radiation Equipment

The Office of Radiological Health (ORH) inspects x-ray facilities for compliance with Article 175 of the New York City Health Code for the protection of the health and welfare of the patient, operator and general public. There are approximately 7000 registered sites in New York City possessing x-ray units for patient diagnosis and treatment.

The NYC Health Code is being amended to assure compatibility with the NYS Sanitary Code regulations on x-ray equipment and the federal regulations as to equipment performance standards. To achieve this compatibility, the amendments to Article 175 incorporate the language or intent of the following regulations:

[1] There are currently 34 Agreement State programs.

- NYS Sanitary Code regulations for x-ray equipment as contained in 10 NYCRR §16.58 (effective 2/4/2004); and

- Food and Drug Administration (FDA) regulations as to the x-ray equipment performance standards as contained in 21 CFR Part 1020 (and as so stated in the NYS Sanitary Code § 16.58).

In addition, Article 175 of the Health Code is being amended to:

- Comply with a NYS Comptroller Audit Report (2001-N-9) recommendation that all new x-ray facilities be inspected by ORH prior to initiating clinical x-ray exams; and,

- Delineate the specific protocols to be followed in calibration of x-ray therapy units, and specify the content of the x-ray therapy calibration reports to be reviewed by ORH.

AMENDMENTS TO THE HEALTH CODE

I. Radioactive Materials

Sections 175.02 and 175.03 of the NYC Health Code are being amended to address the NRC rule, "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2002 (amending 10 CFR §§ 20.1003; 20.1201). The definition of "shallow dose equivalent" is being revised (§175.02) and the method for calculation (§175.03) is being updated.

The definition of "Shallow dose equivalent" in §175.02 is being changed to read as follows: *"Shallow dose equivalent" (H_s), which applies to the external exposure of the skin <u>of the whole body</u> or <u>the skin of</u> an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm2)*. This amendment is required to achieve compatibility with the 2002 revised NRC definition found in 10 CFR §20.1003. For purposes of external exposure, "whole body" means head, trunk (including male gonads), arms above the elbow, or legs above the knee. "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

The method for calculating shallow-dose equivalent is being updated in §175.03 to state that the assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. This change achieves compatibility with the revised NRC occupational dose limits for adults found in 10 CFR §20.1201.

Also, § 175.03 of the NYC Health Code is being amended to address the NRC rule: "Respiratory Protection and Controls to Restrict Internal Exposures" 10 CFR Part 20 amendment (64 FR 54543; 55524) that became effective February 2, 2000 (amending 10 CFR §§ 20.1003; 20.1701 - 20.1704; adding 20.1705 and amending Appendix A to Part 20).

The NYC Health Code previously did not specify conditions under which licensees should use respirators. Revisions to §175.03 incorporate revised NRC language concerning ANSI standards, and the summing of internal and external radiation doses for ALARA (As Low As Reasonably Achievable) purposes. A statement is being added to §175.03 that an individual user who participates in a respiratory protection program is to be determined medically fit

periodically at a frequency determined by a physician. (See also, "Frequency of Medical Examinations for Use of Respiratory Protection Equipment" (60 FR 7900) that became effective March 13,1995 (amending 10 CFR § 20.1703), which is incorporated within the "Respiratory Protection and Controls to Restrict Internal Exposures" 10 CFR Part 20 amendment). A provision for licensees to consider the impact on workers' industrial health and safety is being added to address OSHA requirements with respect to use of appropriate respiratory protective equipment. Additional requirements are being added to §175.03 regarding breathing air quality and procedures for respirator selection, repair, and quality assurance.

In addition, a large body of definitions relevant to Respiratory Protection and Controls is being added to §175.03 APPENDIX A - Protection Factors For Respirators.

II. Radiation Equipment

Section 175.51(d)(1), (2) of the NYC Health Code is being amended to implement a NYS Comptroller Audit Report (2001-N-9) recommendation that all new x-ray facilities be inspected by the ORH prior to initiating clinical x-ray exams.

To accomplish this, the Health Code is being amended with language to authorize ORH to enforce this new registration policy. ORH registers two types of x-ray facilities in New York City:

1) Facilities such as dental offices, podiatrist offices and veterinary offices, all of which are not legally mandated to have a Quality Control (QC) program in effect for their facility; and
2) Facilities such as medical offices, radiologist offices, chiropractic offices, and other large facilities that must have a functioning and on-going QC program at their facility.

At the time of a new registration, facilities not mandated to have a QC program (i.e., dental, podiatrist, and veterinary facilities) shall not be allowed to initiate clinical patient x-rays until they have passed an ORH inspection and corrected all violations (if any) so noted. At the time of a new registration, facilities required to have a QC program (i.e., large facilities, radiologist's offices, medical doctor's offices, and chiropractor's offices) will be mandated to submit all initial acceptance testing to ORH for review and approval prior to conducting clinical studies.

Section 175.62(d) of the NYC Health Code is being amended to implement the NYS Sanitary Code regulations (i.e., NYS Sanitary Code § 16.58 (a)(7), (8) and (9)) pertaining to fluoroscopic x-ray equipment as to the utilization of a new patient equivalent phantom composition[2], the maximum radiation output rate, and the measurements to be conducted by each facility to determine patient Entrance Skin Exposure (ESE). Also, as per these amendments, fluoroscopic exposure rates for the most frequently performed procedures are now to be conspicuously posted.

Section 175.62(d) of the NYC Health Code is being amended to reflect the utilization of a new patient equivalent phantom. Per NYS Sanitary Code § 16.58 (a)(7), the new phantom adds 0.2 mm copper sheets to the existing 1½ inches Type 1100 aluminum phantom thickness to more

[2] A phantom is an object that behaves in the same manner as human tissue with respect to absorption or scattering of ionizing radiation.

realistically match the x-ray attenuation properties of the human abdomen. Manufacturers of x-ray fluoroscopic units have hardened the x-ray beam quality (i.e., made the x-ray beam penetrate to deeper depths in matter) over the last several years. The existing 1½ thick aluminum phantom due to the hardened x-ray beams does not simulate the attenuation properties of the human abdomen, hence, necessitating the addition of material to the 1½ inches of aluminum.

Section 175.62(d) of the NYC Health Code is being further amended to implement the language adopted in the NYS Sanitary Code §16.58 (a)(8) that conforms to the FDA fluoroscopic performance standards as reflected in 21 CFR §1020.32 (d), (e)(1), (2) (59 FR 26402, effective May 19, 1995). The NYS Department of Health has succinctly codified the FDA changes, and ORH is adopting the same language in its amendments. These performance standards mandate the maximum radiation output rate that the fluoroscopic equipment is not to exceed, determined by: 1) date of manufacture of the fluoroscopic equipment, and 2) whether a high-level boost mode is present on the equipment. The NYC Health Code is amended to reflect these more restrictive regulations as outlined in §16.58 (a)(8) of the NYS Sanitary Code.

Also, per NYS Sanitary Code §16.58 (a)(9), the State requires that patient ESE values be measured for each fluoroscopic unit and be posted. This requirement to post is to make the fluoroscopic operators aware of the typical exposures for different body sizes. Accordingly, §175.62(d) of the NYC Health Code is being updated to reflect this NYS Sanitary Code change in posting requirements.

Section 175.62(h)(1)-(2) of the NYC Health Code is being amended to implement the language adopted in NYS Sanitary Code §16.58(a)(12), (13) as to:

1) The new methodology for conducting compliance measurements for the high and low contrast resolution standards for fluoroscopic equipment; and,
2) The utilization of a new high contrast test tool, measuring high contrast resolution in line pairs per millimeter (lp/mm).

Reflecting the medical physicist's testing methods in determining high and low contrast resolution for fluoroscopic units, the State changed the testing methodology as to the fluoroscopic operating parameters (for example, determining resolution in the magnification mode of operation) and changed the test tool used to determine high contrast resolution. The NYC Health Code is being updated to reflect this more professional method in measuring the resolution performance of fluoroscopic units.

Finally, §175.64(g)(8)(ii), (iv) of the NYC Health Code is being amended to specify the use of x-ray therapy protocols developed by the American Association of Physicists in Medicine (AAPM) to be followed by each facility in conducting the annual radiation output measurement for each therapy unit, and to delineate the minimal content that should be contained in each annual calibration report by the facility for review by ORH inspectors. These provisions of the Health Code are also being modified to be more comprehensive as to the content of x-ray therapy output calibration reports and more specific as to the methodology employed in the actual output calibration measurements.

Each facility utilizing the specialized x-ray units for patient cancer treatment (denoted as LINACs) must make annual output calibrations for each unit and save these reports for review by ORH. The AAPM has published professional guidance for therapy calibration protocols that should be utilized when calibrating LINACs. If followed, the AAPM protocols result in the validity of the actual numerical value for radiation output to have an uncertainty of +/- 5%. The AAPM protocols are published in peer-reviewed journals and so represent the best collective reasoning and knowledge of the top medical physicists working in radiation therapy. Prior to this amendment, Article 175 (specifically, §175.64(g)(8)(ii)) did not delineate specific protocols to be followed during calibration of the LINACs. The amended section is now specific as to the AAPM protocols that may be followed by facilities during calibration of their LINAC units. Also, there is confusion as to the exact content of each calibration report that is to be generated and reviewed by ORH. By amending § 175.64 (g)(8)(iv), the section now accurately reflects the content of the calibration report to be retained by the facility for inspection purposes. Both changes were more in the form of clarification of existing ORH inspection standards.

The adopted rule is as follows:

Note - Matter in brackets **[ ]** is to be deleted.
Matter <u>underlined</u> is new.

RESOLVED, that subdivision (a) of Section 175.02 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, as last amended by resolution, on the tenth of March, two thousand five, be and the same hereby is amended, to be printed together with explanatory notes, to read as follows:

§175.02 Definitions

(a) As used in this Code, the following definitions shall apply:

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(200) "Shallow dose equivalent" (H_s), which applies to the external exposure of the skin <u>of the whole body</u> or <u>the skin of</u> an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm2) **[**averaged over an area of 1 square centimeter**]**.

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Notes: Subdivision (a) of Section 175.02 was amended on September 26, 2006, to modify the definition of "shallow dose equivalent" to ensure compatibility with the revised NRC definition as published in the Federal Register, dated April 5, 2002, titled "Revision of the Skin Dose Limit", 67 FR 16298, that became effective April 5, 2002 (amending 10 CFR §§ 20.1003; 20.1201).

RESOLVED, that Section 175.03 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, as last amended by resolution, on the seventh of June, nineteen hundred ninety-four be, and the same hereby is amended, to be printed together with explanatory notes, to read as follows:

§175.03 Standards for protection against radiation

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(c) *Occupational dose limits*.
(1) *Occupational dose limits for adults*.
(i) Except for planned special exposures pursuant to §175.03(c)(6), the licensee or registrant shall control the occupational dose to any individual adult from licensed or registered activities to ensure that such dose does not exceed:
(A) an annual limit, which is the lesser of:
(*a*) a total effective dose equivalent of 0.05 Sv (5 rem); or
(*b*) the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue, other than the lens of the eye, equal to 0.5 Sv (50 rem); and
(B) annual limits to the lens of the eye, to the skin <u>of the whole body</u>, and to the <u>skin of the</u> extremities of:
(*a*) an eye dose equivalent of 0.15 Sv (15 rem), and
(*b*) a shallow dose equivalent of 0.5 Sv (50 rem) to the skin <u>of the whole body</u> or to <u>the skin of</u> any extremity.

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(iii) **[**The assigned deep dose equivalent and shallow dose equivalent shall be determined as follows for that portion of the body receiving the highest exposure**]**
<u>The assigned deep dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure</u>:

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(h) *Respiratory protection and controls to restrict internal exposure in restricted areas*.
(1) *Use of process or other engineering controls*. The licensee or registrant shall use <u>to the extent practicable,</u> process or other engineering controls, such as containment<u>, decontamination,</u> or ventilation, to control the concentrations of radioactive material in air.

(2) *Use of other controls*. When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee or registrant shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:
(i) control of access; or
(ii) limitation of exposure times; or
(iii) use of respiratory protection equipment; or
(iv) other controls.

If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

(3) *Use of individual respiratory protection equipment.* (i) If the licensee or registrant uses respiratory protection equipment to limit intakes pursuant to §175.03(h)(2):

(A) Except as provided in §175.03(h)(3)(i)(B), the licensee or registrant shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

(B) If the licensee or registrant wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration or has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, the licensee or registrant shall submit an application to the Department for authorized use of that equipment **[**,**]**. The application must include **[**including**]** a demonstration by licensee testing **[**,**]** or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

(C) The licensee or registrant shall implement and maintain a respiratory protection program that includes:
(*a*) air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate **[**exposures**]** doses; and
(*b*) surveys and bioassays, as **[**appropriate**]** necessary, to evaluate actual intakes; and
(*c*) testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use; and
(*d*) written procedures regarding respirator selection **[**fitting**]** **;** fit testing; inventory and control, storage, issuance **[**,**]**; maintenance, repair and testing of respirators, including testing for operability immediately prior to each use; supervision and training of **[**personnel**]** respirator users; monitoring, including air sampling and bioassays, and breathing air quality; and quality assurance and recordkeeping; and
(*e*) determination by a physician **[**prior to initial fitting of respirators, and at least every 12 months thereafter,**]** that the individual user is **[**physically able**]** medically fit to use the respiratory protection equipment**[**.**]** prior to initial fitting of a face sealing respirator; before the first field use of non-face sealing respirators and either every 12 months thereafter, or periodically at a frequency determined by a physician.
(*f*) Fit testing, with a fit factor 10 times the APF for negative pressure devices, and a fit factor greater than or equal to 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency of at least once per year. Fit testing must be performed with the face-piece operating in the negative pressure mode.

(D) The licensee or registrant shall issue a written policy statement on respirator usage covering:
(*a*) the use of process or other engineering controls, instead of respirators; and
(*b*) the routine, nonroutine, and emergency use of respirators; and
(*c*) **[**the length of**]** limitations on periods of respirator use and relief from respirator use.

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(F) The licensee or registrant shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use **[**and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed**]**. When selecting respiratory devices, the licensee shall provide for low temperature work environments, and the concurrent use of other safety or radiological protection equipment or skin protection, when needed. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

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(ii) When estimating exposure of individuals to airborne radioactive materials, the licensee or registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to §175.03(h)(2), provided that the following conditions, in addition to those in §175.03(h)(3)(i), are satisfied:

(A) the licensee or registrant selects respiratory protection equipment that provides a protection factor, specified in Appendix A of this section, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Table 1, Column 3 of Appendix B of this section. However, if the selection of respiratory protection equipment with a protection factor greater than **[**the**]** this multiple of peak concentration is inconsistent with the goal specified in §175.03(h)(2) of keeping the total effective dose equivalent ALARA, the licensee or registrant may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. **[**The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.**]** In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the initially estimated dose, the corrected value must be used. If the dose is later found to be less than the initially estimated dose, the corrected value may be used.

(B) The licensee or registrant shall obtain authorization from the Department before **[**assigning respiratory**]** using assigned protection factors in excess of those specified in Appendix A of this section. The Department may authorize a licensee or registrant to use higher protection factors on receipt of an application that:

(*a*) describes the situation for which a need exists for higher protection factors, and
(*b*) demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

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(4) *Further restrictions on the use of respiratory protection equipment*. The Department may impose restrictions, in addition to those in §175.03(h)(2) **[**and**]** , §175.03(h)(3) and in Appendix A to §175.03 to:
(i) ensure that the respiratory protection program of the licensee is adequate to limit **[**exposures of**]** doses to individuals **[**to**]** from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and
(ii) limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

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§ 175.03 APPENDIX A Protection Factors For Respirators
Footnotes:

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2. **[**Only for shaven faces and where nothing interferes with the seal of tight-fitting facepieces against the skin.**]** The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face, face-piece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator face-piece. Hoods and suits are excepted.

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9. Appropriate protection factors shall be determined, taking into account the design of the suit and its permeability to the contaminant under conditions of use. **[**There shall be a standby rescue person equipped with a respirator or other apparatus appropriate for the potential hazards and communications equipment whenever supplied-air suits are used.**]** Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with communications devices and respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

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Definitions:

"Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

"Assigned protection factor" or "APF" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

"Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.
"Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the face-piece only when a negative pressure is created inside the face-piece by inhalation.

"Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

"Filtering face-piece" or "dust mask" means a negative pressure particulate respirator with a filter as an integral part of the face-piece or with the entire face-piece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

"Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.
"Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

"Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

"Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

"Loose-fitting face-piece" means a respiratory inlet covering that is designed to form a partial seal with the face.
"Negative pressure respirator" or "tight fitting respirator" means a respirator in which the air pressure inside the face-piece is negative during inhalation with respect to the ambient air pressure outside the respirator.

"Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator. "Powered air-purifying

respirator" or "PAPR" means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

"Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the face-piece when the positive pressure is reduced inside the face-piece by inhalation.

"Qualitative fit test" or "QLFT" means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

"Quantitative fit test" or "QNFT" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

"Self-contained breathing apparatus" or "SCBA" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

"Supplied-air respirator" or "SAR" or "airline respirator" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

"Tight-fitting face-piece" means a respiratory inlet covering that forms a complete seal with the face.

"User seal check" or "fit check" means an action conducted by the respirator user to determine if the respirator is properly sealed to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamylacetate check.

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Notes: Subdivisions (c) and (h) and Appendix A of Section 175.03 were amended on September 26, 2006, to maintain compatibility with NRC requirements as published in the Federal Register, dated October 7, 1999, titled, "Respiratory Protection and Controls to Restrict Internal Exposures", 64 FR 54543; 64 FR 55524, dated October 13, 1999, that became effective February 2, 2000 (amending 10 CFR §§ 20.1003; 20.1701-.1704; adding 20.1705 and amending Appendix A to Part 20).

RESOLVED, that subdivision (d) of Section 175.51 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, as last amended by resolution, on the seventh of June, nineteen hundred ninety-four, be and the same hereby is amended, to be printed together with explanatory notes, to read as follows:

§ 175.51. Registration and inspection of installations with radiation equipment; other permitted activities.

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[(d) New Registrations. (1) Facilities without a current certificate of registration shall apply for registration at least thirty (30) days before establishing the installation and/or installing the x-ray equipment. (2)**]**

(d) Facilities at which either the operator or location will be changed shall apply for a new registration at least thirty (30) days prior to such change.

(1) Facilities without a current certificate of registration shall apply as follows:
No registrant shall apply x-rays to treat or diagnosis any patient's medical condition at a facility that does not possess a current, non-expired Certificate of Registration from the Department. This shall not prohibit the installation of radiation-producing equipment by a registrant at a facility solely for testing purposes by medical physicists.

i. All new facilities possessing radiation-producing equipment, excluding dental, podiatric, and veterinary facilities, shall apply for a certificate of registration at least thirty (30) days prior to the 'expected start date' for clinical operation of the facility.

ii. The applicant for registration shall submit the following information:

A. a completed application form; and

B. a medical physicist report detailing the results of initial quality control tests conducted on all radiation-producing equipment in the facility. In this context, the initial quality control tests shall be the sum of all quality control tests mandated to be conducted for the facility type at daily, weekly, monthly, semiannual, annual and biennial frequencies. In addition, a radiation protection survey shall be conducted for each room housing a radiographic unit. In this context, a medical physicist shall be an individual possessing a current, non-expired CRESO certification in New York State , or a license to practice the specialty of diagnostic medical physics in New York State.

iii. The Department has the right to refuse to grant a facility's registration until such time as the facility's physicist report contains all quality control mandated tests as submitted by an individual licensed in New York State or possessing a CRESO certification in New York State.

iv. Upon completion of the review process for the submitted quality control tests by the facility, if reasons exist to refuse authorization to register the facility's radiation-producing equipment for clinical usage, the facility shall be notified of the reasons for such a decision by the Department in writing.

(2) All new dental, podiatric, and veterinary facilities without a current certificate of registration shall apply for a new registration at least thirty (30) days before establishing the installation and/or installing the x-ray equipment. All new dental, podiatric, and veterinary facilities shall be

prohibited from commencing diagnostic clinical examinations until such time that the facility has complied with items (i) and (ii) below:

i. New facilities shall file a completed application form with the Department; and

ii. Prior to any clinical usage of radiation-producing equipment, all such new facilities shall be inspected by the Department and shall correct all deficiencies noted at the time of such inspection.

iii. The Department shall have the right to refuse to issue a certificate of registration to any facility that refuses to allow the Department to conduct an inspection of all of the facility's x-ray equipment and/or refuses to correct any violations of the Health Code noted during the inspection provided for in subparagraph (ii).

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Notes: Subdivision (d) of Section 175.51 was amended on September 26, 2006, in order to implement a NYS Comptroller's Audit Report (2001-N-9) recommendation that all new x-ray facilities be inspected by the Department prior to initiating clinical x-ray exams.

RESOLVED, that Section 175.62 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, as last amended by resolution, on the twenty-first of March, two thousand one, be and the same hereby is amended, to be printed together with explanatory notes, to read as follows:

§ 175.62. Fluoroscopy.

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(d) *Entrance exposure rate limits*. **[**The exposure rate as measured with a patient phantom composed of 3.8 cm (1.5 in.) of Type 1100 aluminum in a 18 cm(7 in) square or an equivalent device shall not exceed 12.9E-4 C-kg-1 (5 Roentgens) per minute except during recording of fluoroscopic images or during activation of optional high level control. The maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 25.8 E-4 C-kg-1 (10 Roentgens) per minute except as follows:

(1) Equipment certified in accordance with 21 CFR Part 1020 and having an optional high level control is limited to a maximum output of 12.9 E-4 C-kg-1 (5 Roentgens) per minute unless the high level control is activated and an audible signal to that effect is provided.

(2) Certified equipment without automatic exposure rate is limited to 12.9 E-4 C-kg-1 (5 Roentgens) per minute unless the high level control is activated and an audible signal to that effect is provided.

(3) When the high level control is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 20 Roentgens per minute.**]**

(1) The fluoroscopic exposure rate when measured under the following conditions shall not exceed 5 Roentgens per minute:

(i) the controls are set to the dose rate mode used for the fluoroscopic procedure most commonly performed on that fluoroscopic unit; and

(ii) the image intensifier is set to the largest field of view; and

(iii) the image intensifier is at 12 inches (30 cm) above the tabletop or the over table fluoro tube is at a source to image distance normally used for an average patient; and

(iv) a patient phantom composed of 1 and ½ inch (3.8 cm) thickness of Type 1100 aluminum and 0.02 inch (0.5 mm) thickness of copper or an equivalent device is completely intercepting the useful beam; and

(v) the measurement is made at the measurement location specified in 21 CFR Section 1020.32(d)(3).

(vi) If the exposure rate cannot be measured, the exposure integrated for one minute under the same conditions as subparagraph (i) or paragraph (7) shall not exceed 5 Roentgens.

(2) The maximum exposure rate measured in air shall not exceed 10 Roentgens per minute, when measured in the manner as specified in 21 CFR Section 1020.32(d) (3), except as follows:

(i) Equipment manufactured before May 19, 1995 and certified in accordance with 21 CFR Part 1020 and having an optional high level control is limited to a maximum output of 5 Roentgens per minute unless the high level control is activated and an audible signal to that effect is provided. When the high level is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 20 Roentgens per minute.

(ii) Certified equipment manufactured after May 19, 1995 with automatic exposure rate and having an optional high level control is limited to a maximum output of 10 Roentgens per minute unless the high level control is activated and an audible signal to that effect is provided. When the high level control is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 20 Roentgens per minute.

(iii) Certified equipment manufactured after May 19, 1995 without automatic exposure rate is limited to 5 Roentgens per minute unless the high level control is activated and an audible signal to that effect is provided. When the high level control is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 20 Roentgens per minute.

(3) With the system configured for the most frequently performed fluoroscopic procedure, exposure rates shall be measured with each of the following attenuators in the beam:

(i) 0.75 inches (19 mm) of aluminum (pediatric patient -- 25 kg.),

(ii) 1.50 inches (38 mm) of aluminum (small adult patient -- 50 kg.),

(iii) 1.50 inches (38 mm) of aluminum and 0.02 inches (0.5 mm) of copper (average adult patient -- 75 kg.),

(iv) 1.50 inches (38 mm) of aluminum and 0.08 inches (2.0 mm) of copper (large adult patient -- 100 kg.),

(v) 1.50 inches (38 mm) of aluminum and 0.08 inches (2.0 mm) of copper and 0.12 inches (3.0 mm) of lead (for maximum fluoroscopic exposure rate only).

The fluoroscopic exposure rates for the most frequently performed procedure shall be posted so that they are conspicuous to the operator.

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(h) *Contrast tests.* (1) **[**The high contrast resolution of the fluoroscopic system shall be capable of resolving a minimum mesh number of 24 for the center of the beam and 20 for the edges using a test tool composed of 8 groups of copper or brass mesh screening ranging from 16 to 60 lines per inch set in plastic or an equivalent device. (2) The low contrast performance of the fluoroscopic system shall be capable of resolving a minimum hole size of 3 mm using a test tool composed of a 1.0 mm aluminum sheet with two sets of four holes of dimension 1.0, 3.0, 5.0 and 7.0 mm and a patient equivalent phantom or an equivalent device.**]** The spatial resolution of the fluoroscopic system shall be measured using a test tool composed of a line pair (lp) plate with discreet line pair groups and a maximum lead foil thickness of 0.1 mm or an equivalent device. The test tool shall be placed on a 0.75 inch (19 mm) thickness of type 1100 aluminum, large enough to completely intercept the useful beam, with the test tool 12 inches (30 cm) from the entrance surface of the image receptor assembly. If the system has variable source-to-image distance (SID), the measurement SID shall not exceed 40 inches (100 cm). The image receptor of the fluoroscopic system shall be operated in the six inches (15 cm) field of view (FOV) to conduct this test. If six inches (15 cm) FOV is not available, the system shall be operated in the smallest FOV that exceeds the six inches (15 cm) FOV. The minimum spatial resolution at the center of the beam for all FOVs shall be determined by the following equation:

2 lp/mm x (6 inches (15cm)/size of FOV used) = minimum number of lp/mm.

(2) The low contrast performance of the fluoroscopic system shall be capable of resolving a minimum hole size of 3 mm using a test tool composed of a 1.0 mm aluminum sheet with two sets of four holes of dimension 1.0, 3.0, 5.0 and 7.0 mm and a phantom composed of a 1 and ½ inch (3.8 cm) thickness of Type 1100 aluminum large enough to completely intercept the useful beam or an equivalent device. The test tool shall be 12 inches (30 cm) from the entrance surface of the image receptor assembly. The image receptor of the fluoroscopic system shall be operated

in the six inches (15 cm) FOV to conduct this test. If six inches (15 cm) FOV is not available, the system shall be operated in the smallest FOV that exceeds the six inches (15 cm) FOV.

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Notes: Subdivisions (d) and (h) of Section 175.62 were amended on September 26, 2006, to conform with the requirements of the New York State Sanitary Code § 16.58 for fluoroscopic equipment, and FDA performance standards in 21 CFR 1020.32.

RESOLVED, that subdivision (g) of Section 175.64 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, as last amended by resolution, on the seventh of June, nineteen hundred ninety-four be, and the same hereby is amended, to be printed together with explanatory notes, to read as follows:

§ 175.64. Therapeutic radiation machines.

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(g) *Therapeutic radiation machines: photon therapy systems capable of operating at 500 kV and above and/or electron therapy systems capable of operating at 500 keV and above.*

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(8) *Full calibration measurements*.

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(ii) To satisfy the requirement of § 175.64(g)(8)(i), full calibration shall include all measurements required for annual calibration by "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40," Medical Physics 21(4):581-, 1994, or any successor protocol**[**;**]**. Additionally, the facility shall conduct the output calibration for the therapeutic radiation machine's photon and electron beam modes according to the protocol as outlined in AAPM Report Task Group Report 21 ("A Protocol for the Determination of Absorbed Dose from High-Energy Photon and Electron Beams" Task Group 21 (TG21), Radiation Therapy Committee of American Association of Physicists in Medicine, published in Medical Physics, Volume 10(8), Nov/Dec 1983); or, AAPM Report Task Group Report 51(TG51) ("Protocol for Clinical Reference Dosimetry of High-Energy Photon and Electron Beams", Medical Physics, Volume 29(9), September 1999) or any successor to these documents.

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(iv) The registrant shall maintain a record of each calibration for the duration of the certified registration. The record shall include the date of the calibration, the manufacturer's name, model and serial number or other unambiguous identification of the therapeutic radiation machine **[**and of the instruments used to calibrate the therapeutic machine**]** along with the instrument's certificate of calibration, all measured beam output data collected during the calibration, the

derivation for all the correction factors (as delineated in AAPM Reports TG 21 or TG 51 or any successor publication) applied to the 'measured beam output data' in the calculation of the therapeutic radiation machine's beam output dose rate (the latter shall be conducted for each photon and electron beam clinically utilized at the facility), and the signature of the radiation therapy physicist named on the certified registration.

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Notes: Paragraph (8) of subdivision (g) of Section 175.64 was amended on September 26, 2006, in order to specify the use of x-ray therapy protocols developed by the American Association of Physicists in Medicine to be followed by each licensed facility in conducting the annual radiation output measurement for each therapy unit, and to delineate the minimal content that should be contained in each annual calibration report by the facility for review by Department inspectors.

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